REMARKS

After entry of the present Amendment, claims 1, 4-11, 16-19, 26, 28, 30-34, 37, 39, 40, 45, and 47-72 remain pending in the application. In the July 8, 2002, Office Action, the Examiner rejected claims 1, 4-11, 16-19, 26, 28, 30-34, 37, 39, 40, 45, and 47-55. Applicants have amended claims 1, 5, 6, 7, 8, 11, 16, 26, 28, 32, 37, 39, 40, 45, 47, 48, 49, 52, 56 and 57, canceled claims 19 and 34, and presented new claims 58-72 for consideration. Applicants respectfully request reexamination and reconsideration.

Claim Objections

Claim 56 stands objected to because of the following informalities: "'third' should be deleted in line 4 of the claim" and "in line 8 of the claim, '[body from ambient]' should be deleted." Applicants have amended claim 56 to delete "third" on line 4 and "body from ambient" on line 8, as recommended by the Examiner.

Claim Rejections Under 35 U.S.C. § 112

Claim 57 stands rejected under 35 U.S.C. § 112, first paragraph, for allegedly "containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains...to make and/or use the invention." Applicants respectfully traverse the rejection and also amend claim 57.

Amended claim 57 reads, "A method as in claim 56, further comprising: engaging a third piezoelectric sensor with the patient, at a location remote from the first sensor; sensing physiological signals and environmental noise with the third sensor; and comparing the physiological signals and environmental noise from the first sensor with the physiological signals and environmental noise from the third sensor to determine locations of the first and third sensors on the patient."

Comparison of signals from piezoelectric sensors at multiple locations on a patient to determine locations of the sensors is described in several places in the specification. For example, the description starting on page 8, line 13, explains how sensor data from multiple parts of the body may be compared to isolate energy contributions originating from the heart. Energy spectra data collected by a sensor

located near a patient's foot, for example, can be compared to energy spectra data from a sensor near the patient's chest to isolate energy data from the heart. Since energy from respiration will generally be recorded by the sensor near the chest, but not by the sensor near the foot, data from these two sensors can be distinguished and the locations of the sensors relative to the patient can be determined.

As amended claim 57 is described in sufficient detail in the specification to enable one skilled in the art to make and use the invention, Applicants respectfully submit that claim 57 satisfies the requirements of 35 U.S.C. § 112. Applicants, therefore, respectfully request reconsideration of claim 57.

Claim Rejections Under 35 U.S.C. § 102(b)

Claims 1, 5-8, 16-19, 32, 37, 39, 40 and 56 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Bryars et al., U.S. Patent No. 5,807,267, issued August 8, 1995 (hereinafter "Bryars"). Applicants respectfully traverse this rejection.

Bryars generally discloses a pulse rate monitor to be worn around the wrist. The monitor includes a sensor assembly 2, including a pair of piezo sensors 307A and 307B, both of which contact the wrist 1 of a user. One sensor 307A is configured to contact the radial artery of the user and sense the radial pulse. The other sensor 307B is attached to a bridge configured to straddle the radial artery so that the sensor 307B does not detect a pulse in the artery but detects "only noise from local body motion." (See column 4, lines 51-67, and Fig. 3.)

Applicants' amended independent claim 1 includes, "An apparatus for passively monitoring physiology of a patient, the apparatus comprising: at least two sensors, each comprising a piezoelectric film, for sensing physiological signals from the patient and environmental noise from an environment around the patient, wherein at least one sensor is disposed along a patient supporting surface for coupling with the patient so as to sense the physiological signals and at least one sensor comprises an environmental sensor for sensing the environmental noise external to the patient;...."

Applicants' independent claim 26 includes, "A passive physiological monitoring apparatus for monitoring physiology of a patient, the apparatus comprising: plural sensors for sensing data by placing at least one of the plural sensors in a patient supporting surface for coupling with the patient and at least one of the plural sensors in a position for sensing ambient noise without physiological signals, each of the plural sensors comprising a piezoelectric film comprising polyvinylidene fluoride (PVDF), wherein the plural sensors comprise a pair of sensors for sensing the sensed data from the patient and for separately sensing the ambient noise from an environment around the patient;...."

Applicants' independent claim 37 includes, "A method for passively monitoring physiology of a patient, the method comprising: coupling a first piezoelectric sensor with the patient, the first sensor disposed along a patient supporting surface; placing a second piezoelectric sensor in a location for sensing environmental noise from an environment around the patient; sensing physiological signals and environmental noise with the first sensor and environmental noise with the second sensor;...."

Finally, Applicants' independent claim 56 includes, "A method for passively monitoring physiology of a patient, the method comprising: engaging a first piezoelectric sensor with the patient by coupling the patient with a patient supporting surface including the first sensor; engaging a second piezoelectric sensor in a location for sensing environmental noise but not physiological signals from the patient; sensing physiological signals and environmental noise with the first sensor and environmental noise with the second sensor;...." Support for the amendments to claims 1, 26, 37 and 56 may be found throughout the originally filed specification. No new matter has been introduced.

Among other elements of independent claims 1, 26, 37 and 56, Bryars does not disclose or suggest at least one sensor for sensing environmental or ambient noise. Instead, Bryars describes one sensor 307A for sensing a radial pulse and another sensor 307B for detecting "only noise from local body motion." Furthermore, Bryars

does not disclose or suggest a patient supporting surface, but instead describes an apparatus configured like a wrist watch.

For the above reasons, Applicants submit that Bryars does not disclose, teach or suggest each and every element of independent claims 1, 26, 37 and 56. Accordingly, claims 1, 26, 37 and 56 are not anticipated by Bryars. Similarly, claims 5-8, 16-19 and 32 (which depend from claim 1) and claims 39 and 40 (which depend from claim 37) are also not anticipated by Bryars. Therefore, Applicants respectfully request the withdrawal of all rejections of claims 1, 5-8, 16-19, 32, 37, 39, 40 and 56 under 35 U.S.C. § 102(b).

Claim Rejections Under 35 U.S.C. § 103(a)

Claims 4, 26 and 28 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Bryars in view of Zanetti et al., U.S. Patent No. 4,989,611, issued February 5, 1991 (hereinafter "Zanetti"). Applicants respectfully traverse this rejection.

Zanetti generally discloses a cardiac compression wave measuring system including a polyvinylidine pieozoelectric film. As explained above, however, Bryars does not disclose, teach or suggest apparatus as described in claims 1 or 26 of the present invention. For example, Bryars does not disclose at least one sensor for sensing environmental or ambient noise. Bryars also does not teach or suggest a patient supporting surface.

Therefore, even if Zanetti's polyvinylidine pieozoelectric film were combined with Bryars as suggested by the Examiner, the invention of claim 4 (which depends from claim 1), claim 26 and claim 28 (which depends from claim 26) would not be obtained. Applicants further submit that the references of record contain no suggestion or motivation to combine the references as proposed by the Examiner.

Claims 9-11 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Bryars in view of Zanetti and further in view of Scanlon, U.S. Patent

No. 5,684,460, issued November 4, 1997 (hereinafter "Scanlon '460"). Applicants respectfully traverse this rejection.

Scanlon '460 generally describes a motion and sound monitor and stimulator, including a fluid-filled sensor pad 12, typically in the form of a mattress and including a pressure transducer 14 connected to a water chamber of the sensor pad 12 via a hose 16 (column 4, lines 6-10 and 38-43). Scanlon '460 does, therefore, describe a fluid-filled sensor pad 12 as suggested in the Office Action. Again, however, Bryars does not disclose or suggest either at least one sensor for sensing environmental noise or a patient supporting surface.

Therefore, even if Scanlon '460's pad were combined with Bryars, in view of Zanetti, the invention of independent claim 1 and dependent claims 9-11, would not be obtained. Applicants further submit that the references of record contain no suggestion or motivation to combine the references as proposed by the Examiner. In fact, Applicants submit that the modification proposed by the Examiner would render the invention in Bryars unsatisfactory for its intended purpose. Even if it were possible, adding a fluid-filled pad with a water chamber, pressure transducer, and hose to a pulse monitor configured as a wrist watch would render the watch unsatisfactorily cumbersome.

Claims 30 and 31 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Bryars in view of Zanetti and further in view of Trimmer et al., U.S. Patent No. 4,245,648, issued January 20, 1981 (hereinafter "Trimmer"). Applicants respectfully traverse this rejection.

Trimmer generally discloses a method and apparatus for measuring blood pressure and pulse rate and does describe measurement of pulse wave transit time. Trimmer, however, teaches away from a combination as proposed by the Office Action. Trimmer describes measuring a pulse pressure wave using a sensor head 12 having two spaced-apart transducers (column 2, lines 63-68, column 3, lines 1-2). Consistent measurements using Trimmer's method depend on placement of the sensor head 12 on "an exteriorized artery where the muscular tissue is least influential; i.e., on the brachial artery high on the arm" (column 3, lines 25-32). By contrast, Bryars describes a wrist

watch sensor device for placement on the radial artery. As Trimmer explains, "As the arteries propagate outward from the aorta, they become more and more muscular...." Therefore, because the radial artery is significantly distal to, and more muscular than, the brachial artery, Trimmer teaches away from using its method or apparatus on the radial artery.

Additionally, as explained above, Bryars does not disclose or suggest either at least one sensor for sensing ambient noise or a patient supporting surface. Therefore, even if Trimmer's method and apparatus for measuring blood pressure were combined with Bryars in view of Zanetti, the invention of independent claim 26 and claims 30 and 31 (which depend from claim 26) would not be obtained.

Claims 33 and 34 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Bryars in view of Zanetti and further in view of Scanlon, U.S. Patent No. 5,853,005, issued December 29, 1998 (hereinafter "Scanlon '005"). Applicants respectfully traverse this rejection.

Scanlon '005 generally discloses an acoustic monitoring system, using a fluid-filled pad, which may be incorporated into a stretcher, wheelchair or other device. Again, however, neither Bryars nor Scanlon '005 disclose, teach or suggest at least one sensor for sensing ambient noise, as described in claim 26 of the present invention. Therefore, even if Scanlon '005 were combined with Bryars in view of Zanetti, the invention of claim 26 and claims 31 and 34 (which depend from claim 26) would not be obtained. Furthermore, the cited references contain no suggestion or motivation to combine as proposed by the Office Action.

Claims 45 and 47-55 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Bryars in view of Trimmer. Applicants respectfully traverse this rejection.

As discussed above, Trimmer does describe measurement of pulse-wave travel times. Again, however, Trimmer teaches away from using its apparatus or method on the radial artery, as described by Bryars. Therefore, the references should not be combined because Trimmer teaches away from doing so.

Applicants further submit that there is no suggestion or motivation in the cited references to create the combination proposed by the Office Action. Even if Bryars and Trimmer were combined, however, the invention of claims 1 and 37 would not be obtained. Neither Bryars nor Trimmer teaches or suggests at least one sensor for sensing environmental noise or a patient supporting surface. Therefore, since the invention of claims 1 and 37 would not be obtained, the invention of claims 45 and 47-55, which variously depend from claims 1 and 37, would not be obtained.

For the foregoing reasons, Applicants respectfully request that all rejections of claims 4, 9-11, 26, 28, 30-31, 33-34, 45 and 47-55 based on 35 U.S.C. § 103(a) be withdrawn.

New Claims

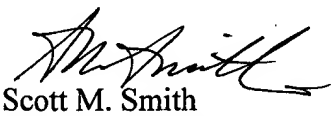
In order to more fully claim the novel aspects of the present invention, Applicants have added claims 58-72. These added claims contain no new subject matter and are fully supported by the specification.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Previously amended) An apparatus for passively monitoring physiology of a patient, the apparatus comprising:

at least two sensors, each comprising a piezoelectric film, for sensing physiological signals from the patient and environmental noise **[signals]** from an environment around the patient, wherein at least one sensor is disposed along a patient supporting surface for coupling with the patient so as to sense the physiological signals and at least one sensor comprises an environmental sensor for sensing the environmental noise external to the patient;

a converter communicating with the at least two sensors for converting the physiological signals and environmental noise **[signals]** into digital signals;

a processor communicating with the converter for isolating physiological digital signals from the digital signals by comparing the digital signals between the at least two sensors to provide physiological data; and

a monitor communicating with the processor for displaying the physiological data in real-time.

Claims 2 and 3 previously canceled.

5. (Previously amended) The apparatus of claim 1, further comprising at least one band-pass filter coupled with the at least two sensors for filtering out **[at least one of]** the environmental noise **[signals]**.

6. (Previously amended) The apparatus of claim 5, further comprising a pre-amplifier coupled with the band-pass filter for pre-amplifying at least one of the physiological **[and environmental]** signals.

7. (Previously amended) The apparatus of claim 1, where the physiological signals and environmental noise **[signals]** are selected from the **[a]** group consisting of mechanical, thermal and acoustic signals.

8. (Previously amended) The apparatus of claim 1, wherein the physiological **[and environmental]** signals may be used to indicate any of blood pressure, cardiac output, cardiac function, internal bleeding, respiratory rate, pulse rate, apnea, and body temperature **[signals and combinations thereof]**.

11. (Amended) The apparatus of claim 10, wherein the fluid comprises **[is]** a non-reactive substance selected from the **[a]** group consisting of gel, water, air, foam, rubber, and plastic **[or combinations thereof]**.

Claims 12-15 previously canceled.

16. (Previously amended) The apparatus of claim 1, wherein the processor further comprises a frequency Fourier transform for transforming the physiological digital signals **[data]** into frequency data.

17. (Previously amended) The apparatus of claim 16, further comprising a microcomputer for recording, analyzing and displaying the frequency data to enable on-line assessment of the frequency data and real-time response to the frequency data.

18. (Previously amended) The apparatus of claim 1, wherein the piezoelectric film is positioned under the patient at various locations.

Please cancel claim 19 without prejudice or disclaimer.

Claims 20-25 previously canceled.

26. (Previously amended) A passive physiological monitoring apparatus for monitoring physiology of a patient, the apparatus comprising:

plural sensors for sensing data by placing at least one of the plural sensors **[on]** in a patient supporting surface for coupling with the patient and at least one of the plural sensors in a position for sensing ambient noise without physiological signals, each

of the plural sensors comprising a piezoelectric film**[, the piezoelectric film comprising a polymer for sensing data from the patient and converting the sensed data into voltage measurements, the polymer]** comprising polyvinylidene fluoride (PVDF), wherein the plural sensors **[consist of]** comprise a pair**[s]** of sensors for sensing the sensed data from the patient and for separately sensing the ambient noise from an environment around the patient;

a converter communicating with **[the]** each of the plural sensors for converting the sensed data and the sensed ambient noise into signals;

a computing device communicating with the converter for receiving and computing the signals and for outputting computed data; and

instrumentation communicating with the computing device for real-time interaction with the device and for display of the computed data.

Claim 27 previously canceled.

28. (Previously amended) The apparatus of claim 26, wherein at least one of the plural sensors is disposed on a substrate selected from the **[a]** group consisting of **[an item of clothing,]** a stretcher, a bed, a litter, an operating table, a gurney, **[a cervical collar, body armor, body protection gear, a uniform, an extraction device, exercise equipment,]** an item of furniture, a cushion, a seat and a seatback.

Claim 29 previously canceled.

32. (Previously amended) The apparatus of claim 1, wherein the at least two sensors comprise an array of sensors distributed over different locations along the patient supporting surface for measuring and monitoring the physiological signals **[sensed data]** from the patient.

Please cancel claim 34 without prejudice or disclaimer.

Claims 35 and 36 previously canceled.

37. (Previously amended) A method for passively monitoring physiology of a patient, the method comprising:

coupling **[placing]** a first piezoelectric sensor **[in contact]** with the patient, the first sensor disposed along a patient supporting surface;

placing a second piezoelectric sensor in a location for sensing environmental noise from an environment around the patient, **[near to but not in contact with the patient]**;

sensing physiological signals and environmental noise **[signals]** with the first sensor and environmental noise **[signals]** with the second sensor;

converting the physiological signals and environmental noise **[signals]** into physiological and environmental digital signals;

isolating the physiological digital signals from the environmental digital signals by subtracting environmental signals sensed by the second sensor from the signals sensed by the first sensor; and

displaying the physiological digital signals.

Claim 38 previously canceled.

39. (Previously amended) The method of claim 37, further comprising filtering out the environmental noise **[signals]** with a band-pass filter.

40. (Amended) The method of claim 37, wherein **[the]** sensing the physiological signals and environmental noise comprises sensing mechanical, thermal and acoustic signals.

Claims 41-44 previously canceled.

45. (Previously amended) The method of claim 37, further comprising:

coupling **[placing]** a third sensor with **[on]** the patient, at a location remote from the first sensor; and

measuring a pulse-wave velocity with the first and third sensors.

Claim 46 previously canceled.

47. (Previously added) An apparatus as in claim 1, wherein the at least two sensors comprise at least three sensors, two sensors disposed along the patient supporting surface so as to couple with **[contacting]** the patient at different locations and one sensor **[in]** positioned for sensing environmental noise from an environment around the patient **[but not in contact with the patient]**.

48. (Previously added) An apparatus as in claim 47, wherein the processor compares physiological signals and environmental noise **[signals]** sensed by the two sensors and environmental noise **[signals]** sensed by the one sensor, so as to isolate the physiological signals from the environmental noise.

49. (Previously added) An apparatus as in claim 1, wherein a first sensor is disposed at a first location along the patient supporting surface and a second sensor is disposed at a second location along the patient supporting surface, and wherein the processor determines a pulse-wave velocity in response to a physiological signal time difference between the first sensor and the second sensor.

52. (Previously added) A method as in claim 37, further comprising:

engaging a third sensor with the patient, at a location remote from the first sensor;

comparing physiological signals and environmental noise **[signals]** from the first and third sensors; and

using the comparison to reduce the environmental noise **[signals]** and amplify the physiological signals.

56. (Previously added) A method for passively monitoring physiology of a patient, the method comprising:

engaging a first piezoelectric sensor with the patient by coupling the patient with a patient supporting surface including the first sensor;

engaging a second **[third]** piezoelectric sensor in a location for sensing environmental noise but not physiological signals from the patient **[near to but not in contact with the patient]**;

sensing physiological signals and environmental noise **[signals]** with the first sensor and environmental noise **[signals]** with the second sensor;

isolating the physiological signals from the **[body from ambient]** environmental noise **[signals]** by subtracting environmental noise **[signals]** sensed by the second sensor from the signals sensed by the first sensor; and

displaying the physiological digital signals.

57. (Previously added) A method as in claim 56, further comprising:

engaging a third piezoelectric sensor with the patient, at a location remote from the first sensor;

sensing physiological signals and environmental noise **[signals]** with the third sensor; and

comparing the physiological signals and environmental noise **[signals]** from the first sensor with the physiological signals and environmental noise **[signals]** from the third sensor to determine locations of the first and third **[second]** sensors on the patient.

--58. (Added) An apparatus as in claim 1, wherein the at least one sensor disposed along the patient supporting surface for coupling with the patient senses the physiological signals from the patient through at least one layer of clothing.

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59. (Added) An apparatus as in claim 1, wherein the at least one sensor comprises a grid of 32 sensors.

60. (Added) An apparatus as in claim 59, wherein each of the 32 sensors is rectangular.

61. (Added) A method as in claim 37, wherein sensing physiological signals comprises sensing signals selected from the group consisting of blood pressure, heart rate, respiratory rate, pulse pressure and body temperature.

62. (Added) A method as in claim 56, wherein engaging the first piezoelectric sensor with the patient and sensing physiological signals from the patient occur through at least one layer of clothing.

63. (Added) A method as in claim 56, wherein sensing physiological signals comprises sensing signals selected from the group consisting of blood pressure, heart rate, respiratory rate, pulse pressure and body temperature.

64. (Added) An apparatus for passively monitoring physiology of a patient, the apparatus comprising:

a patient supporting surface; and

a plurality of piezoelectric sensors disposed along the supporting surface for sensing physiological signals from the patient and environmental noise from an environment around the patient;

a converter coupled with the sensors for converting the physiological signals and environmental noise into digital signals; and

a processor coupled with the converter for isolating physiological digital signals from the digital signals by comparing the digital signals between the sensors to provide physiological data.

65. (Added) An apparatus as in claim 64, further comprising a monitor coupled with the processor for displaying the physiological data.

66. (Added) An apparatus as in claim 64, wherein the physiological signals comprise heart beat motion and respiratory motion.

67. (Added) An apparatus as in claim 64, wherein the physiological data are selected from the group comprising heart rate, blood pressure, respiratory rate, pulse pressure, body temperature and cardiac function.

68. (Added) An apparatus as in claim 64, wherein the plurality of sensors comprises a grid of 32 sensors.

69. (Added) A method for passively monitoring physiology of a patient, the method comprising:

providing a plurality of piezoelectric sensors disposed along a patient supporting surface;

sensing, with the sensors, physiological signals from the patient and environmental noise from an environment around the patient;

converting the physiological signals and the environmental noise into physiological and environmental digital signals;

isolating the physiological digital signals from the environmental digital signals; and

displaying the physiological digital signals as physiological data.

70. (Added) A method as in claim 69, wherein the physiological signals comprise heart beat motion and respiratory motion.

71. (Added) A method as in claim 69, wherein the physiological data are selected from the group comprising heart rate, blood pressure, respiratory rate, pulse pressure, body temperature and cardiac function.

72. (Added) An apparatus as in claim 69, wherein the plurality of sensors comprises a grid of 32 sensors.--